

ACC NEWS

President's Page: The Changing Face of Research

Douglas P. Zipes, MD, FACC

President, American College of Cardiology



It can be difficult to accept change. When we recognize a new trend beginning to reshape our environment, we worry and often speculate on the worst possible outcomes. Balancing a desire for maintaining the present with the inevitability of a new future is often a tough juggling act. Should we have heralded the advent of managed care as a visionary evolution or rejected it as a detriment to the health care of every American? Should physicians unionize, or would doing so deprofessionalize us and damage the sacred doctor-patient relationship, rather than strengthen our position to protect our patients? Should we fear the role that Internet sites are beginning to play in health care, or should we work with them to ensure that the information they offer our patients is backed by our expertise?

And what about research? There can be no doubt that it, too, is undergoing a transformation. . .not just what is researched, such as molecular biology and genetics, but how we go about it. My goal here is to explore the changing face of research, giving equal space to some worries about the ethical dilemmas we may confront and also to the visions of what we may accomplish.

THE OLD MODEL

Not so long ago, academic health centers seemed to have cornered most of the medical research market. Medical scientists almost always worked in academia. It was the hotbed of basic science experiments, the source of most of the papers in the literature, and the place where industry turned to test a new drug, device, or diagnostic advance. From academic health centers came the data on safety and efficacy that industry needed to obtain new product approval by the Food and Drug Administration and to get life-saving therapies and diagnostic procedures accepted as components of everyday patient care.

While medical research was a collaborative effort in those days, there was also an unmistakable line drawn in the sand that kept marketing, sales, and profits separate from clinical investigation. For the most part, that division was laid down by the academic health centers, where concerns over the bottom line, press announcements, and patent applications were eschewed. In fact, when we implanted the first transvenous cardioverter in two patients with monomorphic ventricular tachycardia (1) and had both newspaper and television coverage of the event, I was roundly chastised by my dean for such egregious behavior. The entrepreneurial

spirit had not yet infiltrated our research culture. We were personally to be silent about such advances and let the published manuscript do the talking. Today, many would say that was shortsighted, and perhaps they are right. But research, just for the pure joy of discovery, was the motive. And even now, at least for me, there is still no greater intellectual thrill than creating an hypothesis, testing it at the bench or bedside, finding it to be true, and knowing that you have contributed a bit of information, no matter how small, to the wealth of human knowledge, and that for a brief moment in time, you may be the only person in the world who possesses that tiny fact. The feeling is awesome and motivates me to this day.

CHANGING TIMES

Gradually, over the past few years, several new paradigms for medical research have developed. Increasingly, superb basic science is performed in industry laboratories. By bringing basic science "in house," industry is capable of competing with the academic health centers and even entities like the National Institutes of Health (NIH). In essence, industry has found a market for knowledge acquisition. Take the Human Genome Project for example. Companies like Celera Genomics and Human Genome Sciences are competing with academic health centers and the NIH to patent genetic information that may be used in their future products. Some companies already market genetically derived materials—unquestionably a growth area.

Just as there is certain logic in pharmaceutical and device companies employing their own scientists and performing their own research, there is an inherent appeal in launching clinical trials with the participation of large private practices. Industry no longer automatically turns to academic health centers to conduct clinical trials on new products for several reasons. First, there is large patient volume in these private practices—many willing patients seeking the latest treatment. Second, the doctors in these practices are actual or potential customers of the company sponsoring the research. Basing clinical trials in their examining rooms is an ideal opportunity for industry to expose these physicians to products they may very well prescribe in the future. Third, many of the practices have dedicated staff, funded by the research, that can recruit patients and gather data efficiently. And, finally, the practice can be motivated to make money by performing the industry-funded studies.

THE EFFECTS

Human impulse is to judge—to declare this evolving paradigm either good or bad and then to praise or condemn it. So, the challenge here is to look at this new model, compare it to the old, try to imagine what will happen next in both best- and worst-case scenarios, and to watch carefully as it unfolds.

There are some obvious positives, mostly the products of collaboration and opportunity. As industry has opted to put its dollars into its own laboratories and into private practices, the stigma scientists previously suffered when they chose to work for industry has faded. No longer are the motives of industry-employed researchers closely scrutinized or labeled as greed. Now, working in industry is a viable and acceptable option for young scientists. They present their work at scientific meetings, serve as reviewers and publish in premier journals, and are accepted as colleagues by the academic scientific world. They have assured income and research funds, without the uncertainties accompanying research life in academia. However, the goal of research in industry is to develop pharmaceuticals and devices that will ultimately be products for sale. There is scant interest in pursuing questions that have little foreseeable potential to generate such products, and therefore the work of such scientists must become very focused and restricted. In academia, any interesting question can be a valid topic for initiating research. While the latter is true, it has been said that the problem of being a researcher in academia is that there are no stock options!

Another change in relationships has occurred as private practices have found ways to incorporate research into their patient care. Opportunities for academic health centers and private practices to collaborate have appeared. A private practitioner might team up with a nearby university research team, pooling their expertise. As a result, the lines separating academia from private practice have become much more blurred.

Now, the drawbacks. One of the biggest issues surrounding these changes—and the one that is of most concern to me, given my perspective as the director of cardiology at an academic health center—is their impact on academia. The funneling of research dollars and opportunities away from academia has most definitely contributed to the plight of academic health centers. Industry determines who becomes a researcher of its products, who gets the plaudits for publishing new information and the accoutrements accompanying such activities, and who gets the financial support. Academia also suffers as we lose some of today's best and brightest scientists to industry, with its steady funding, its financial rewards, and its entrepreneurial spirit. This loss has, or will, diminish the effort given to basic research.

In addition, academic health centers are losing control over an area in which they excel, an area where the ethical forks in the road of potential conflicts of interest are familiar landmarks. There are true dangers in having research

conducted by the people or in the facilities that have the potential to personally profit from positive outcomes. An extraordinary number of the papers we read in medical journals and the presentations we hear at scientific meetings are provided by experts who stand to benefit financially from the research they are conducting. The natural rebuttal to the potential impropriety of that fact is that these are the most knowledgeable people on the topic. That is why industry used them as researchers and consultants in the first place, or why they have formed their own company, and therefore they should be presenting the data. While this potential conflict of interest is worrisome, it can—and must—be surmounted. But it does require ethical astuteness from all parties, an understanding of the need to make public one's affiliations and one's financial relationship with industry. Such information, usually considered private, is, under this new model for research, pertinent.

It must be noted that there are potential conflicts of interest in academia as well. In addition to their desire to excel academically, researchers are increasingly encouraged to work with their university technology transfer offices to patent and commercialize their discoveries. They can face pressures similar to their industrial counterparts.

WHAT NOW?

This paradigmatic change in the way we conduct the research that determines how we treat our patients may represent untold opportunities to advance medical care. Or it may represent another blow to our already struggling medical system. Regardless, it does present an ethical and practical challenge that we must rise to meet. The task before us now is to be vigilant and open-minded as these changes continue to unfold and to speak up when we detect a pothole in the road ahead. The academician and private doctor working in research must collaborate and do it in a way that avoids any conflict of interest. Because perception often replaces reality, the best way to avert an ethical problem is to be open about all relationships that might be perceived as a conflict. It may be helpful to use the yardstick of whether one would be upset if the relationship were first divulged in a headline in the *New York Times*. Ultimately, excellent research will win out, and neither academia nor industry can afford to have failures because it is too expensive in the long run for both. So, in the final analysis, objectivity, accountability, and honesty must be the guideposts in this changing world of research.

Reprint requests and correspondence: Douglas P. Zipes, MD, FACC, Indiana University School of Medicine, Krannert Institute of Cardiology, 1111 W. 10th Street, Indianapolis, Indiana 46202.

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